

REMARKS

Claims 1-10 and 13-20 have been examined. Claims 11 and 12 have been canceled, without prejudice, for filing in a divisional application. Claims 1 and 13 have been amended. Reconsideration of the claims, as amended, is respectfully requested.

Election/Restriction

Claims 11 and 12 have been canceled, without prejudice, pursuant to the restriction requirement.

Claim Objections

Claim 10 has been objected to for not providing antecedent basis for "the mold." Applicant respectfully traverses this objection since claim 1 from which claim 10 depends recites the use of "a mold." Hence, it is requested that this objection be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 1, 2, 4-7, 10, 13, 14, 16 and 20 have been rejected under 35 U.S.C. § 102 as being anticipated by Duncan. This rejection is respectfully traversed in part and overcome in part.

As now amended, independent claim 1 claims a method for treating an infected implant area of a knee joint. The method utilizes a tibial component having a tray, a central stem and a posterior stabilizing component. The central stem is inserted into the tibia (along with the antibiotic impregnated material). This provides stability to the tibial component while it is attached to the tibia. Further, the tibial component may be easily removed when ready to replace it with a permanent implant. Further, the antibiotic impregnated material is used to treat the infected area.

The method of claim 1 also uses a femoral component that is formed of an antibiotic impregnated material using a mold. The femoral component comprises a one-piece,

integral design that includes two outer surfaces and a center section having a recess that is configured to interact with the tibial component. The femoral component is attached to the femur so as to completely cover the distal femur using an antibiotic impregnated material, thus treating any infection around the femur. Also, the antibiotic impregnated femoral component has more stability by encapsulating the entire distal femur. Furthermore, since the femoral component is attached to the femur using additional antibiotic impregnated material, it treats any infection around the femur.

When the tibial component and the femoral component are interfaced, the posterior stabilizing protrusion fits into the recess of the femoral component, with the two outer nails resting on the tray. This configuration provides anterior and posterior as well as lateral and medial stability to the knee joint.

In summary, the method of claim 1 produces a temporary knee joint that is highly stable at three interfaces while also being easily removable when the infection has subsided. These three interfaces are between the tibial component and the tibia, between the femoral component and the femur and between the femur component and the tibial component.

In contrast, the Duncan patent describes a far different method - one that results in an unstable knee joint. For example, the tibial component of Duncan does not extend into the tibia as required in claim 1. Further, the tibial component does not have a tray with a protrusion, nor does Duncan have a femoral component that includes two outer surfaces and a recess for receiving the protrusion. More importantly, the Duncan design has two separate rails that are not connected and do not cover the entire distal end of the femur. Also, each of these rails has a metal runner. As such, with the Duncan knee joint, areas of instability exist between the metal rail within the additional antibiotic impregnated material runner, the femoral components and the femoral bone surfaces, the tibial component and the tibia bone interface, and between the tibial component and the femoral component. Indeed, the Duncan knee joint is highly susceptible to becoming dislocated.

Furthermore, each of the Duncan metal runners are known to aggravate infection.

Hence, claim 1, which has been amended to include various features which provide both stability and ease of subsequent removal, is distinguishable and in condition for allowance. Claims 2, 4-7 and 10 depend from claim 1 and are distinguishable for at least the same reasons.

Independent claim 13 claims a method for treating an infected implant area of a knee joint. The method of claim 13 includes a tibial component and a femoral component similar to those recited in claim 1. Hence, claim 13 is distinguishable for at least the same reasons. Claims 14, 16-18 and 20 depend from claim 13 and are distinguishable for at least the same reasons.

Claim Rejections - 35 U.S.C. § 103

Claims 3 and 15 have been rejected under 35 U.S.C. §.103 as being unpatentable over Duncan in view of Letot. Claims 3 and 15 recite that the tibial component is constructed of polyethylene. The Office Action asserts that it would have been obvious to make the Duncan knee joint out of polyethylene simply because Letot describes a tibial component that is constructed of polyethylene. Applicant respectfully disagrees.

First, the Letot mobile bearing design is not in the same field of endeavor as the present invention. The claims of the present invention deal with a temporary knee joint that is used to treat an infected area. Letot deals with a sterile knee that receives a permanent implant. Further, the Letot design is intended to be used with a metal femoral component, not one constructed of an antibiotic impregnated material. One of skill in the art would not be motivated to use the Letot implant in treating an infected total knee replacement because of the exposed metal and significant dead space recesses that exist between the mobile polyethylene bearing and the metal base plate. This configuration of the Letot system permits bacteria to easily penetrate its recesses, making it difficult for antibiotics and the body's defense mechanisms to reach the infected areas.

One of skill in the art would clearly not combine two cement and metal femoral runners of Duncan with a metal and polyethylene mobile bearing device in order to produce a sterile, temporary knee implantation. Hence, it is requested that the section § 103 rejection of claims 3 and 15 be withdrawn.

Claims 8, 9 and 19 have been rejected under 35 U.S.C. § 103 as being obvious in view of Duncan and Shaffner. Claims 8 and 19 depend from claim 1 and claim 19 depends from claim 13. As previously described, the Duncan patent fails to teach the limitations as found in these independent claims. Since the Shaffner patent also fails to teach such limitations, claims 8, 9 and 19 are distinguishable for at least the same reasons.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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/darin j gibby/
Darin J. Gibby
Reg. No. 38,464

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, CA 94111-3834
Tel: 303-571-4000
Fax: 415-576-0300
DJG/cl
60886361 v1